

Full HD VIDEO-CAMERA COMBINED WITH **LED LIGHT-SOURCE** 

# ELICA III

#### Camera

Real Full HD camera sensor: 1920 x 1080p

**LED Light source** 

Easy user interface LCD touch screen

#### Easy user interface

via camera head button

Recording Still image (compress JPEG), movie clip (compress H.264)





#### MGB Endoskopische Geräte GmbH Berlin

Schwarzschildstr. 6, 12489 Berlin, Germany

Tel: +49-30-6392-7000 / Fax: +49-30-6392-7011 / E-mail: sales@mgb-berlin.de

#### MGB Endoscopy Co. Ltd. (MGB Seoul)

5F, Shinsegae I&C Digital Center 61 Digital-ro 31 gil, Guro-gu, SEOUL 08375, REPUBLIC OF KOREA Tel: +82-2-6300-6410 / Fax: +82-2-6499-7789 / E-mail: mgbseoulsales@ebionet.com www.mgb-berlin.de



#### **Camera Head**

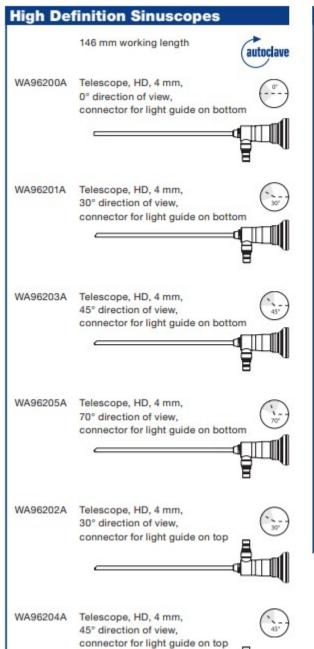
Image Sensor	1/3 " CMOS, Progressive scanning	
Sensor Pixels	1920*1080 pixels	
Camera Head Button	2 Programmable buttons	
Lens Adaptor	Standard C-Mount	
Camera Cable	3m	
Weight	280g	
Dimension [W*D*H]	41.6 * 41.4 * 88.5mm	

#### **Light Source**

Lamp type	LED
Lamp life time	Over 50,000 hours
Color temperature	5,000K
Light outlets	Compatible with wolf type

#### Main unit

Order-No.	670-51500		
Dimensions(w*d*h)	380*440*140mm		
Weight	11.0Kg		
User interface	7" LCD touch screen		
Power supply	100~240 VAC, 50/60 Hz		
	Medical safety standards :		
Safety	EN60601-1, Class I, Type BF		
	Medical EMC standards:		
	EN60601-1-2		
Operating temperature	+10 °C ~ +40 °C		
Power consumption	2.0A – 1.0A		
Operating humidity	30% ~ 75%		
Extend of delivery	Power cord		
	Instruction for use		



#### **Accessories**

WA96208A Handle, for sinuscopes,

autoclavable



WA03200A Light-guide cable,

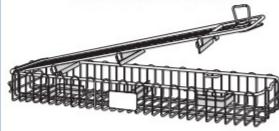
size S, plug type, 3 m, CF type



A5940 Instrument basket,

for 2 telescopes,

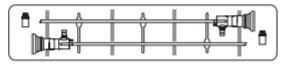
outer dimensions: 462 x 52 x 105 mm



WA05990A Instrument tray,

for 2 telescopes,

outer dimensions: 446 x 49 x 88 mm



#### **EC** Certificate

## Directive 93/42/EEC, Annex II excluding (4) Full Quality Assurance System



#### **Berlin Cert**

Prüf- und Zertifizierstelle für Medizinprodukte GmbH

hereby certifies that



### MGB Endoskopische Geräte GmbH Berlin

Schwarzschildstraße 6, 12489 Berlin

has implemented and uses a quality assurance system for the following scope of application:

Design, production and final inspection of surgical products (see Appendix)

The audit in accordance with Annex II of MDD 93/42/EEC (report no. A-17-131-SZ) provided confirmation that the requirements of Annex II of MDD 93/42/EEC have been fulfilled. The Manufacturer has to be inspected periodically by the notified body according the requirements of Annex II, Article 5 of MDD 93/42/EEC. The manufacturer is allowed to use this certification in his process for the declaration of conformity.

The manufacturer is allowed to place the CE-mark on the above mentioned products in combination with the identification No. **0633**.

issued on:

2017-12-22

valid from:

2017-12-28

valid to:

2022-12-21







# Appendix to certificate Z-17-131-S-R II-E from 2017-12-22

		Classification		
product/product category	UMDNS	l s/m	II a	II b
Endoscopes and accessories			$\boxtimes$	
HF-surgical devices Aristo HF35, HF4000L, HF4000B, HF2000B, HF800B	11-490			×
Insufflators Fencer, ML-G, ML-GX and accessories (tubes, cannulas, others)	12-144		×	
sterile products for single use			×	
Trocars and accessories (trocar sleeves, trocar stop)	14-154	0	$\boxtimes$	
HF-surgical devices - accessories GRP-handpieces	11-494			×
Accessories for suction and irrigation systems (sheaths, inserts, cannulas, tubes, handles, adapter, connection parts)	17-676	D	$\boxtimes$	



#### CERTIFICATE

#### **Berlin Cert**

Prüf- und Zertifizierstelle für Medizinprodukte GmbH



hereby certifies that

### MGB Endoskopische Geräte GmbH Berlin

Schwarzschildstraße 6, 12489 Berlin, Germany

has implemented and uses a quality management system for the following scope of application

> Development, manufacturing and distribution of surgical instruments and devices including accessories for diagnostics, surgery and HF surgery, as well as optical systems, sheaths, instruments, devices and accessories for minimal invasive surgery and rigid endoscopy

The audit (report no. A-17-131-S) provided confirmation that the requirements in the standard

#### **DIN EN ISO 13485:2016**

Medical devices - Quality management systems Requirements for regulatory purposes

have been fulfilled.

Issued: 2019-03-26

Valid from: 2019-04-01

Valid until: 2020-12-21





